



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/285,559 04/02/99 HECHEL

D 3216/75036

EXAMINER

QM12/0730

WELSH & KATZ
120 SOUTH RIVERSIDE PLAZA
22ND FLOOR
CHICAGO IL 60606

ART UNIT	PAPER NUMBER
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3737
DATE MAILED:

07/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/285,559

Examiner

Runa S. Qaderi

Applicant(s)

HECHEL ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/23/01.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watmough et al. in view of Chervitz.

Regarding claims 1-11 Watmough et al. disclose a means and method of applying ultrasound treatment wherein a temperature sensing visual indicator is in contact with the treated tissue, wherein temperature of the skin is indicated by color changes, column 3 lines 21-23 and 30-33. The patent teaches a liquid crystal device that detects the temperature of the skin via color changes. In addition Watmough et al. disclose that frequency of the ultrasound is altered to alter depth and temperature distribution, column 3 lines 37-44. In regard to claim 11 Watmough et al. disclose a computer simulation for determining skin temperature, ultrasound absorption, thermal conduction, and different power settings of the transducer on the temperature distribution inside the tissue during local hyperthermia.

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Watmough et al. differs from the claimed invention in that a securing mechanism via an adhesive backing is not addressed. Other features of the strip that are not addressed in Watmough et al. include the strip further comprising of a plastic sandwich, colored background, and character display. Also Watmough et al. does not teach a color change at a predetermined or threshold temperature.

Chervitz discloses a visual indicator with an adhesive backing, and comprising of a plastic sandwich, colored backing, and displaying numeric characters indicative of temperature change. Chervitz teaches a visual indicator adapted to be disposed on the skin or surface of the body that changes color and displays characters at the threshold temperature of the specific temperature range of the crystal indicator, column 1 line 16. See abstract, column 1 lines 14-17, and column 2 lines 4-9. The patent further teaches that the color spectrum of each liquid crystal indicator are responsive to a different specific temperature range, and the liquid crystal indicator being invisible at temperatures below the threshold temperature. In other words each liquid crystal indicator changes color only at this threshold or predetermined temperature, each indicator having a specific temperature range, column 2 lines 4-17. In addition the adhesive visual indicator of Chervitz is capable of being used with an ultrasound treatment because it is adapted to be disposed on the skin or surface of the body to provide color change due to tissue temperature change

It would have been obvious at the time the invention was made to a person of ordinary skill in the art to determine an average depth of penetration of the ultrasound for the selected frequency, column 5 lines 13-16. Average is construed to mean typical

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or normal in this claim. Watmough et al. teaches a method that is applicable for predicting affected tissue characteristics due to ultrasound treatment. It would have been obvious to a person of ordinary skill in the art to use the temperature-detecting skin surface patch of Chervitz because it provides means for monitoring the ultrasound treatment via detecting when threshold temperature has been reached. Since Watmough et al. already disclosed a means of detected the skin temperature to monitor the ultrasound treatment, it would have been obvious to one of ordinary skill in art to use the skin surface patch of Chervitz because it is an alternative means of detected skin temperature. Also it would have been obvious for a person of ordinary skill in the art to substitute alphanumeric characters for numeric character. Chervitz already discloses a means for displaying a temperature change using characters. Therefore the characters could either be numeric or alphanumeric and in addition any message could be displayed using the alphanumeric characters. Further it would have been obvious to indicate a visual change only at a predetermined temperature in order to monitor ultrasound treatment.

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Claims 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watmough et al. in view of Chervitz as applied to claims 1-11 above, and further in view of Cohen.

Regarding claims 12-17 Watmough et al. in view of Chervitz does not teach a thermochromatic strip that provides an opacity change when a dosage limit of the ultrasound treatment has been reached. Cohen teaches a thermographic or liquid crystal material with an adhesive backing provided in the front side of a pacifier flange that displays a change in color or opacity at or above a predetermined temperature, column 1 and 2. It would have been obvious to indicate an opacity change only at a predetermined temperature in order to monitor ultrasound treatment because it is an alternative means of a visual indication.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Watmough et al. in view of Chervitz as applied to claims 1-11 above, and further in view of Behnke et al.

Regarding claim 18 Watmough in view of Chervitz does not teach the thermochromatic strip further comprising a tab color-coded with the threshold or predetermined temperature. Behnke et al. teaches an analyte test strip that displays color changes to indicate results. A color comparison standard that is attached to the testing device for the quantitative evaluation of the degree of change in color, column 11

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lines 9-11. It would have been obvious for a person of ordinary skill in the art to further comprise the thermochromatic strip with a color comparison tab to easily observe and compare the necessary color change at the predetermined temperature.

Conclusion

Prior Art of Record

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Name, patent number

Navato, 4,030,482

McNaughtan, 4,070,912

Inoue et. al, 4,154,106

Mung-Kuen Luk, 4,198,861

Chervitz, 4,232,684

Luk, 4,302,971

Chervitz, 4,333,477

Nelson, 4,437,471

Klopotek, 5,230,334

Cline, 5,291,890

Bock, 5,618,275

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Marzorati, 5,776,076

Smith, 5,947,988

Silberg, 6,039,048

Slayton et. al, 6,050,943

Gouge et.al, 6,067,371

Cribbs et. al, 6,071,239

Klopotek, 6,113,559

Bechtold et. al, 6,128,523

Brounstein, 6,138,968

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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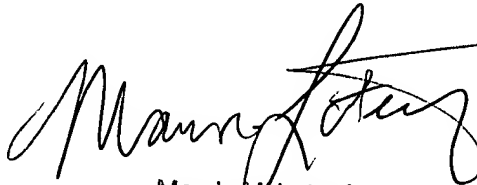
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Runa S. Qaderi whose telephone number is (703) 308-8155. The examiner can normally be reached on Mon-Fri 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on (703) 308-3256. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

RSQ

Runa Shah Qaderi
July 27, 2001



Marvin W. Lateef
Supervisory Patent Examiner
Group 3700

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.